JUN 8 - 2005 K050406

1.4 510(k) Summary of Safety and Effectiveness

Submitted by:	Elizabeth J. Mason Sr. Regulatory Affairs Specialist
Address:	Nobel Biocare USA LLC 22715 Savi Ranch Parkway Yorba Linda, CA 92887
Telephone:	(714) 282-4800, ext. 7830
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Date of Submission:	February 16, 2005
Classification Name:	Endosseous Implant (21 CFR 872.3640)
Trade or Proprietary or Model Name:	NOBELSPEEDY™ Implants
Legally Marketed Device(s):	Nobel Biocare Endosseous Implants (K041661)

Device Description:
Nobel Biocare's NOBELSPEEDY™ Implants are threaded, root-form dental implants intended for use in the upper and lower jaw to support prosthetic devices, such as artificial teeth, in order to restore esthetics and chewing function to partially or fully edentulous patients.

NOBELSPEEDY™ Implants incorporate a groove on the threads of the implant and have a tapered apex. The implants are machined from commercially pure titanium and are available with a straight contour. NOBELSPEEDY™ Implants have a surface treatment consisting of a titanium oxide layer, (TiUnite®), which extends from the implant threads onto the implant collar.

Nobel Biocare's NOBELSPEEDY™ Implants may be placed in the oral cavity using either a single stage surgical procedure or a two stage surgical procedure. If a single stage procedure is used, the implants may be immediately loaded following insertion where good initial stability of the implant can be obtained. NOBELSPEEDY™ Implants can be placed in soft bone and under-prepared sites.

Indications for Use:
NOBELSPEEDY™ Implants are root-form endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NOBELSPEEDY™ Implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. NOBELSPEEDY™ Implants may be placed immediately and put into immediate function providing that the initial stability requirements detailed in the surgical manuals are satisfied.

NOBELSPEEDY™ Implants are indicated for use in soft bone or whenever immediate or early loading is applied. The NOBELSPEEDY™ Implants incorporate a groove on the implant thread and are preferred over models without the groove in these soft bone indications because bone forms more rapidly in the groove than on other parts of the implant resulting in increased stability when compared to non-grooved implants. In addition, the NOBELSPEEDY™ Implants are preferred in these soft bone indications because bone formation on the TiUnite® surface is more rapid and greater than on machined surface implants resulting in better maintenance of initial implant stability, faster and stronger osseointegration, and higher success rates.

NOBELSPEEDY™ Implants may be tilted up to 45°. When used with angulations between 30° and 45° a minimum of four implants must be used and splinted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 8 - 2005

Nobel Biocare USA LLC
C/O Mr. Herbert Crane
Regulatory Affairs Director
Nobel Bicoare US, Incorporated
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K050406
Trade/Device Name: NOBELSPEEDY™ Implants
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: May 27, 2005
Received: May 31, 2005

Dear Mr. Crane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jennette Y. Richmond M.D.

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3

Indications for Use

510(k) Number (if known): K050406

Device Name: NOBELSPEEDY™ Implants

Indications For Use:

NOBELSPEEDY™ Implants are root-form endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NOBELSPEEDY™ Implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare NOBELSPEEDY™ Implants may be placed immediately and put into immediate function providing that the initial stability requirements detailed in the surgical manuals are satisfied.

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K050406